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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|-------------------------------|--------------------------------------|
| 09/970,580 | 10/04/2001 | Arnold C. Bilstad | DDR 5455-DIV (1417B P 649) | 2598 |
| 7590 | 05/19/2005 | | | EXAMINER JASTRZAB, KRISANNE MARIE |
| Mark J. Buonaiuto, Esq. Assistant General Counsel, Law Department BAXTER INTERNATIONAL INC. One Baxter Parkway, DF3-2E Deerfield, IL 60015 | | | ART UNIT 1744 | PAPER NUMBER |
| DATE MAILED: 05/19/2005 | | | | |

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | |
|------------------------------|-------------------------------|------------------|
| Office Action Summary | Application No. | Applicant(s) |
| | 09/970,580 | BILSTAD ET AL. |
| | Examiner Krisanne Jastrzab | Art Unit 1744 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 04 March 2005.

2a) This action is FINAL. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 18-33 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5) Claim(s) _____ is/are allowed.

6) Claim(s) 18-33 is/are rejected.

7) Claim(s) _____ is/are objected to.

8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some * c) None of:

1. Certified copies of the priority documents have been received.

2. Certified copies of the priority documents have been received in Application No. _____.

3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) Notice of References Cited (PTO-892)

2) Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.

4) Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.

5) Notice of Informal Patent Application (PTO-152)

6) Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 18-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nablo U.S. patent No. 3,780,308.

Nablo teaches method and apparatus for sterile filling of packages with low energy electrons on the order of 50 to 150 keV. Sterile containers are provided to a sterile, isolated area constructed to contain e-beams therein, where a filler spout is maintained in aseptic condition and the package port and filler spout are irradiated during filling with the electrons. An activated gas can also be created in the region utilizing UV-rich gas such as xenon. After sterile filling is complete, the packages are sealed and conveyed away. The process is automatic and can be performed repeatedly. See column 5, line 60 through column 6 and the claims. Nablo is silent as to the material for filling the packages, but it would have been well within the purview of one of ordinary skill in the art to determine that this system is applicable to fluids as a filler "spout" is employed and as sterile filling of fluids is particularly well recognized in the art.

Response to Arguments

Applicant's arguments filed 3/4/2005 have been fully considered but they are not persuasive.

Applicant argues that Nablo does not teach filling the port of the pre-sterilized container while "in the active sterile field", however, the Examiner would disagree. Applicant argues that "zone 4" of Nablo is not an active field and that only the dispensing port is maintained within an active field during filling, and that the container moves through an inactive field during transfer from head A to head B. First, the Examiner would point out that Applicant claims a "pre-sterilized container", and Nablo is "pre-sterilizing" his container at head A, not filling the container. Secondly, the

Examiner would assert that “zone 4” is clearly and definitely maintained as an active field, and she would point Applicant to column 5, lines 60-68 where Nablo specifically recites an ozonated atmosphere prevailing in zone 4, or another gaseous irradiation. See also column 6, lines 60-68 and column 7, lines 4-10. The Examiner would further point out that the entire zone is taught as being shielded, a step only necessary if the entire zone is active (see column 6, lines 49-52). Finally, the Examiner would maintain that Fig. 5(b) and the corresponding citations above clearly set forth the placement of the filling port within an active field during the entire filling process.

Applicant further argues that the newly added language of “controlled sterilizing field” overcomes the rejection over Nablo with the assertion that such language makes explicit the parameters of the sterilizing field such as a beam diameter, however, the Examiner would maintain that the newly added language fails to clearly require such limitations of the field parameters, and that the sterilization are of Nablo can also be considered a “controlled sterilizing field” because it occurs in a specific, contained location with set activation parameters and penetration depths.

Conclusion

This is a RCE of applicant's earlier Application No. 09/970580. All claims are drawn to the same invention claimed in the earlier application and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the earlier application. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action in this case. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no, however, event will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Krisanne Jastrzab whose telephone number is 571-272-1279. The examiner can normally be reached on Mon.-Wed. 6:30am-4:00pm and alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John Kim can be reached on 571-272-1142. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Krisanne Jastrzab
Primary Examiner
Art Unit 1744

May 16, 2005